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The Trans-Pacific Partnership: The Death-Knell of Generic Pharmaceuticals?

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The Trans-Pacific Partnership: The Death-Knell of Generic Pharmaceuticals?

ABSTRACT

As global commerce continues to expand, many states find international trade agreements to be a useful tool to facilitate this continued expansion. Trade agreements permit developing or poorer nations to establish robust, mutually beneficial trade relationships with powerful economies such as the United States. In the face of regional competition from China, several nations bordering the Pacific Ocean, including the United States, have reached a far-reaching trade agreement called the Trans-Pacific Partnership (TPP). This Note will focus on one particular piece of the TPP: the pharmaceutical trade and the international availability of generic medicines. The TPP has the potential to dramatically alter intellectual property laws in the signatory nations and may have a disruptive effect on the availability of generic pharmaceuticals worldwide. This Note analyzes the potential for this problem and proposes an alternative mechanism in which signatory nations are granted automatic licenses for certain medicines they deem essential.

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I. INTRODUCTION

In 2008, the United States entered into negotiations with Chile, New Zealand, Singapore, and Brunei for a proposed free trade agreement called the Trans-Pacific Partnership (TPP).¹ Since then, the agreement has expanded to include several other nations with a significant trade presence in the Pacific region, including Australia, Peru, Vietnam, Malaysia, Mexico, Canada, and Japan.² A final agreement was reached on October 5, 2015, making the TPP one of the largest trade agreements in the world.³

The goal of this trade agreement was to expand industry in developing Pacific nations and stimulate trade between all signatory nations.⁴ Many commentators have viewed this trade agreement as a strategic move to counter-balance China's influence in the Pacific region.⁵ Negotiations for the TPP occurred privately, with the contents being accessible only to each nation's trade representatives

1. NEW ZEALAND MINISTRY OF FOREIGN AFFAIRS AND TRADE, TRANS-PACIFIC STRATEGIC ECONOMIC PARTNERSHIP AGREEMENT: UNDERSTANDING THE P4—THE ORIGINAL P4 AGREEMENT (2012), <http://www.mfat.govt.nz/Trade-and-Economic-Relations/2-Trade-Relationships-and-Agreements/Trans-Pacific/0-history.php> [<http://perma.cc/UL37-9CYN>] (archived Feb. 26, 2015).

2. IAN F. FERGUSSON, CONG. RESEARCH SERV., R42694, THE TRANS-PACIFIC PARTNERSHIP (TPP) NEGOTIATIONS AND ISSUES FOR CONGRESS 1 (2014) [hereinafter FERGUSSON, TPP].

3. Jackie Calmes, *Trans-Pacific Partnership Is Reached, but Faces Scrutiny in Congress*, N.Y. TIMES (Oct. 6, 2015), <http://www.nytimes.com/2015/10/06/business/trans-pacific-partnership-trade-deal-is-reached.html> [<http://perma.cc/B5GN-L9TF>] (archived Oct. 23, 2015); FERGUSSON, TPP, *supra* note 2.

4. Calmes, *supra* note 3, at 2.

5. Lydia DePilis, *Everything You Need to Know About the Trans-Pacific Partnership*, WASH. POST (Dec. 11, 2013), <http://www.washingtonpost.com/blogs/wonk-blog/wp/2013/12/11/everything-you-need-to-know-about-the-trans-pacific-partnership> [<http://perma.cc/DZ57-HUX8>] (archived Feb. 26, 2015); Alex Frangos, *Interest Builds in Pacific Trade Zone*, WALL STREET J. (Oct. 8, 2010), <http://www.wsj.com/news/articles/SB10001424052748704011904575538003964028436?mg=reno64-wsj&url=http%3A%2Fonline.wsj.com%2Farticle%2F%2FSB10001424052748704011904575538003964028436.html> [<http://perma.cc/NH4P-9S9K>] (archived Feb. 26, 2015); Jane Kelsey, *The Trans-Pacific Partnership as a Lynchpin of US Anti-China Strategy*, FOREIGN CONTROL WATCHDOG (Dec. 2011), <http://www.converge.org.nz/watchdog/28/06.htm> [<http://perma.cc/H23T-R238>] (archived Feb. 26, 2015); Mireya Solís, *The Containment Fallacy: China and the TPP*, BROOKINGS (May 24, 2013), <http://www.brookings.edu/blogs/up-front/posts/2013/05/24-china-transpacific-partnership-solis> [<http://perma.cc/KPM9-XF8Q>] (archived Feb. 26, 2015).

and their advisors.⁶ In the fall of 2013, the anti-secrecy organization WikiLeaks first leaked a negotiator's draft of the Intellectual Property Rights Chapter of the TPP.⁷ In October of 2014, it leaked a new version of this chapter that was purported to be current as of May of that year.⁸ Finally, on October 9, 2015, just four days after the final agreement was reached, WikiLeaks released what it claimed was the final Intellectual Property Rights Chapter.⁹ The final official text was released to the public on January 26, 2016, revealing the accuracy of the final leaked version.¹⁰ The leaked documents revealed the contentious nature of this agreement, particularly with regard to its intellectual property (IP) provisions.¹¹ In total, the leaked documents demonstrated at least nineteen points of disagreement between the United States and the other parties during the negotiations of the TPP's IP provisions.¹²

While the TPP's IP provisions largely track existing U.S. IP law, the final provisions expand upon it in several key areas.¹³ Additionally, the TPP raises existing global standards created by the Agreement on Trade-Related Aspects of Intellectual Property Rights

6. DePilis, *supra* note 5.

7. *Id.*

8. *Secret Trans-Pacific Partnership Agreement (TPP): Intellectual Property Rights Chapter*, WIKILEAKS (Aug. 30, 2013) [hereinafter TPP Leak 1], <https://wikileaks.org/tpp/> [<http://perma.cc/EPB3-QNMG>] (archived Oct. 23, 2015); *Secret Trans-Pacific Partnership Agreement: Intellectual Property Chapter Working Document for All 12 Nations with Negotiating Positions*, WIKILEAKS [hereinafter TPP Leak 2], <https://wikileaks.org/tpp-ip2/> [<https://perma.cc/LH4S-D93T>] (archived Feb. 26, 2015).

9. *Trans-Pacific Partnership Agreement (TPP): Intellectual Property Rights Chapter, Consolidated Text*, WIKILEAKS (Oct. 5, 2015) [hereinafter TPP Leak 3], <https://wikileaks.org/tpp-ip3/> [<https://perma.cc/W5MK-XLY8>] (archived Oct. 23, 2015).

10. NEW ZEALAND FOREIGN AFFAIRS AND TRADE, *Trans-Pacific Partnership (TPP)* (2015), <https://www.mfat.govt.nz/en/about-us/who-we-are/treaty-making-process/trans-pacific-partnership-tpp> [perma.cc/AD2U-GSBB] (archived Feb. 1, 2016); M. Ryder Lee, *When Wikileaks Works: Comparing the Leaked Draft of the IP Section of the TPP to the Official USTR Text and the Consequences to Termination Rights in "Phonograms"*, BUTLER SNOW: BIZLITNEWS (Dec. 15, 2015), <http://www.butlersnow.com/2015/12/when-wikileaks-works-comparing-the-leaked-draft-of-the-ip-section-of-the-tpp-to-the-official-ustr-text-and-the-consequences-to-termination-rights-in-phonograms/> [perma.cc/3XSP-HDRD] (archived Feb. 1, 2016); Drew Wilson, *TPP Text: Wikileaks Version Compared to Official Version*, FREEZENET (Dec. 16, 2015), <http://www.freezenet.ca/tpp-text-wikileaks-version-compared-to-official-version/>, [<https://perma.cc/EU6C-2U9Z>] (archived Feb. 1, 2016); see also Krista Hughes, *US Hopes to Release TPP Trade Deal Text in 30 Days: Michael Froman*, INT'L BUS. TIMES (Oct. 10, 2015), <http://www.ibtimes.com/us-hopes-release-tpp-trade-deal-text-30-days-michael-froman-2136072> [<http://perma.cc/VSP5-9U9W>] (archived Oct. 23, 2015).

11. Emma Woollacott, *US Fails to Close TPP Deal as Wikileaks Exposes Discord*, FORBES (Dec. 10, 2013), <http://www.forbes.com/sites/emmawoollacott/2013/12/10/us-fails-to-close-tpp-deal-as-wikileaks-exposes-discord/> [<http://perma.cc/A44E-94GT>] (archived Oct. 23, 2015).

12. *Id.*

13. DePilis, *supra* note 5.

(TRIPS).¹⁴ The IP areas most affected are copyrights, patents, and IP enforcement.¹⁵

One notable change in the IP realm involves the patentability of generic pharmaceuticals.¹⁶ The TPP expands patentability of pharmaceutical products and permits their patent terms to be lengthened by up to five years.¹⁷ This change will potentially reduce the availability of cheap generic medicines or increase the price of available medicines in the signatory nations.¹⁸

The IP enforcement regimes have also likely changed for many nations involved.¹⁹ Member states have to bring their enforcement regimes in line with that of the United States, which mandates stiffer penalties for infringement, including criminal penalties.²⁰

Proponents of the deal have pointed to the economic benefits that the agreement is predicted to bring to member nations.²¹ In addition to denouncing the overall lack of transparency in negotiations, critics have expressed concern with the IP provisions, noting that the lion's share of the anticipated benefits will go to patent and copyright holders, resulting in greater restrictions on the public's freedom to access and use knowledge.²²

Part II of this Note will describe the development of the TPP, focusing on the influential role that the United States played during negotiations. This Part will also discuss the main points of contention among signatories, describing the way this new treaty modifies the current state of global intellectual property law.

Part III will analyze the projected effects of the TPP on the international pharmaceutical trade, focusing in particular on the likelihood that many citizens of Pacific nations will see dramatic, sometimes prohibitive, increases in the prices for prescription drugs. As a result of the increased protections offered to pharmaceutical patent-holders, nations that currently provide cheap pharmaceuticals as part of their national healthcare plans may see generics become more expensive or harder to procure. In analyzing this change in

14. *Id.*

15. *Id.*

16. *Id.*

17. TPP Leak 2, *supra* note 8, arts. QQ.E.1, .12, .16.

18. DePilis, *supra* note 5 (explaining that the TPP would "make the approval process more difficult for generic drug makers and extend protections for biologic medicines.").

19. See FERGUSSON, TPP, *supra* note 2, at 29.

20. *Id.* at 29–30.

21. *Id.* at 3 (suggesting that the TPP would bring comprehensive market access, regional agreement that facilitates trade, regulatory coherence, and a flexible approach to emerging trade issues).

22. James Love, *New Leak of TPP Consolidated Text on Intellectual Property Provides Details of Pandering to Drug Companies and Publishers*, KNOWLEDGE ECOLOGY INT'L (Oct. 16, 2014, 5:03 PM), <http://keionline.org/node/2108> [<http://perma.cc/PLK4-V4W9>] (archived Feb. 26, 2015).

price and availability, this Note will analyze the effects that the TPP's changes will have on consumers in general, as well as focus on the varying ways that different nations will be affected. This Note will also compare the current state of U.S. intellectual property law to the IP laws of other nations and to the recommendations set forth by the TRIPS agreement. In comparing the various regimes, this Note will analyze some of the conflicts that the proposed changes will have with the current laws of the involved nations.

Finally, Part IV will propose an alternative version of the IP provisions that would expressly permit nations to distribute generic pharmaceuticals without fear of an infringement suit. This alternative provision would permit signatory nations to use their discretion and devise national "essential medicines" lists. Each signatory would have the discretion to grant compulsory licenses for pharmaceutical products found on that nation's list. This change would permit private or public entities within each state to devise generic alternatives to essential medicines that may then be cheaply distributed within that nation. In return, the pharmaceutical pioneer that invented the original medicine would receive a royalty as compensation for his or her research and development costs. This Note will provide details regarding how this royalty may appear, and will discuss whether and how this plan could be implemented, and the medical and monetary ramifications such a plan might have for signatory nations and pharmaceutical companies.

II. FACTUAL BACKGROUND

The TPP is a long-negotiated free trade agreement between twelve nations that border the Pacific Ocean, including the United States.²³ Once fully implemented, this will be the largest trade agreement in the world by trade-flow, affecting 40 percent of the world's GDP and 26 percent of the world's trade.²⁴ This Part will describe the events that led to the development of the TPP, focusing primarily on the United States' role, and will discuss the major points of contention among signatories.

A. *Inception and Development of the TPP*

The seeds for the Trans-Pacific Partnership were planted in 2002 when representatives of Singapore, Chile, and New Zealand entered into side negotiations while attending the Asia Pacific Economic

23. DePilis, *supra* note 5.

24. *Id.*

Cooperation (APEC) Leaders Summit in Los Cabos, Mexico.²⁵ Their shared goal was to devise an agreement that would liberalize trade across the Pacific Ocean in order to foster economic development in each of the three nations.²⁶ By 2005, Brunei Darussalam had entered into talks with the original three parties, and on June 3, 2005, the “P4” nations announced that they had signed a trade pact.²⁷ The trade pact was called the Trans-Pacific Strategic Economic Partnership Agreement, or Trans-Pacific SEP, and represented the P4 nations’ shared vision for a future trade expansion in the Asia-Pacific region.²⁸ Pursuant to the agreement, each party promised to eliminate trade barriers and facilitate the movement of goods among signatories, to promote fair competition, to increase investment opportunities in each party’s territory, to establish a cooperative approach to IP rights, and to create an effective mechanism for resolving trade disputes.²⁹ In addition, this agreement affirmed the parties’ commitment to encourage other nations to join the negotiations.³⁰ These original tenets of the Trans-Pacific SEP laid the foundation for the expansive set of multi-party negotiations known as the Trans-Pacific Partnership.³¹

In January 2008, Susan Schwab, the U.S. Trade Representative at the time, announced plans for the United States to commence trade negotiations with the P4, suggesting it might join the actual Trans-Pacific SEP trade pact.³² The introduction of the United States as a negotiating partner enticed several other Pacific nations to join subsequent rounds of negotiations.³³ According to David Skilling, the chief executive of the New Zealand Institute, the addition of an economic heavyweight like the United States gave the relatively small economies of the P4 members a seat at the global negotiating table.³⁴ Subsequently, the combined negotiating team of the P4 and

25. Joint Press Statement, Ministers of Brunei Darussalam, Chile, New Zealand, and Singapore, Brunei Darussalam, Chile, New Zealand and Singapore Conclude Negotiations on a Trans-Pacific Strategic Economic Partnership Agreement (June 3, 2005), <http://web.archive.org/web/20060907090445/http://www.mfat.govt.nz/tradeagreements/transpacepa/transpaceppress.html> [http://perma.cc/22RB-YRCK] (archived Feb. 26, 2015).

26. *Id.*

27. *Id.*

28. *Id.*; Chris Daniels, *First Step to Wider Free Trade*, N.Z. HERALD (Feb. 10, 2008), http://www.nzherald.co.nz/business/news/article.cfm?c_id=3&objectid=10491556 [http://perma.cc/MYR9-V38T] (archived Feb. 26, 2015).

29. Trans-Pacific Strategic Economic Partnership Agreement art. 1.1, 2005, <http://www.mfat.govt.nz/downloads/trade-agreement/transpacific/main-agreement.pdf> [http://perma.cc/X8S5-2CNW] (archived Feb. 26, 2015).

30. *Id.* Preamble.

31. *Id.* art. 1.1.

32. Daniels, *supra* note 28.

33. *Id.*

34. *Id.*

the United States, now referred to as the Trans-Pacific Partnership, began to invite other nations to join them in trade talks.³⁵ In 2008, the P4 invited Australia, Peru, and Vietnam to a round of trade talks that would commence in March of 2009 in Singapore.³⁶

Over the next few years, several more parties joined the TPP, many of which began to view the TPP as an opportunity to strategically counter-balance China's growing economic influence in the Pacific.³⁷ Malaysia joined talks in October of 2010, Canada and Mexico joined in October of 2012, and Japan joined in March of 2013.³⁸ While several other nations, including Thailand and South Korea, considered joining, the final negotiating consortium included twelve countries: Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, the United States, and Vietnam.³⁹ The combined population of these twelve nations is almost 800 million people,⁴⁰ and their combined GDP comprises approximately 40 percent of the world's total GDP.⁴¹ Once implemented, the TPP will be the largest free trade agreement, measured by trade flow, that the United States has ever entered into.⁴²

35. *Id.*

36. Ray Brindal, *Australia to Join Trans-Pacific Trade Bloc*, ALIBABA (Nov. 27, 2008), <http://news.alibaba.com/article/detail/asia/100025812-1-australia-join-trans-pacific-partnership-trade.html> [<http://perma.cc/PGF6-5T6V>] (archived February 26, 2015).

37. DePilis, *supra* note 5; Frangos, *supra* note 5; Kelsey, *supra* note 5; Solís, *supra* note 5.

38. NEW ZEALAND MINISTRY OF FOREIGN AFFAIRS AND TRADE, TRANS-PACIFIC STRATEGIC ECONOMIC PARTNERSHIP AGREEMENT: TPP TALK (2012), <http://www.mfat.govt.nz/Trade-and-Economic-Relations/2-Trade-Relationships-and-Agreements/Trans-Pacific/1-TPP-Talk/0-TPP-talk-10a-Oct-2012.php> [<http://perma.cc/444R-ZFGV>] (archived Feb. 26, 2015); IAN F. FERGUSSON, CONG. RESEARCH SERV., R42694, THE TRANS-PACIFIC PARTNERSHIP (TPP) NEGOTIATIONS 3 (2015); Press Release, Tim Groser, Mexico Joins Trans-Pacific Partnership Negotiations (June 19, 2012), <http://www.beehive.govt.nz/release/mexico-joins-trans-pacific-partnership-negotiations> [<http://perma.cc/X6S9-6LKK>] (archived Feb. 26, 2015); Joshua Meltzer, *Japan to Join the Trans-Pacific Partnership—Finally!*, BROOKINGS (Mar. 18, 2013), <http://www.brookings.edu/blogs/up-front/posts/2013/03/18-japan-joins-trans-pacific-partnership-meltzer> [<http://perma.cc/Q7G8-5BVK>] (archived Feb. 26, 2015).

39. Meltzer, *supra* note 38; TPP Leak 3, *supra* note 9, at 1.

40. Scott Harris, *The TPP Is Coming to Canada (Not That It's Easy to Tell)*, COUNCIL CANADIANS (June 25, 2014, 2:47 PM), <http://canadians.org/blog/tpp-coming-canada-not-its-easy-tell> [<http://perma.cc/SCT8-FZWS>] (archived Feb. 26, 2015).

41. Jacqui Fatka, *Tide Changing on TPP Negotiations*, FARM FUTURES (Dec. 26, 2014), <http://farmfutures.com/blogs-tide-changing-tpp-negotiations-9315> [<http://perma.cc/MAB7-J2SL>] (archived Feb. 26, 2015); Yoko Nishiwaka, *South Korea Mulling U.S.-Led TPP Trade Initiative: Report*, REUTERS (Nov. 13, 2010), <http://www.reuters.com/article/2010/11/14/us-apec-korea-idUSTRE6AD05L20101114> [<http://perma.cc/2P7M-XTX9>] (archived Feb. 26, 2015).

42. Harris, *supra* note 40; see FERGUSSON, TPP, *supra* note 2, at 54.

B. Confidential Negotiations, Missed Deadlines, and the United States' Response

Following the TPP's inception, the parties met more than twenty times to negotiate terms.⁴³ Each party sent trade representatives who were required to maintain strict confidence during negotiations.⁴⁴ According to the Office of the United States Trade Representative (USTR), which represented the United States, each nation signed a confidentiality agreement "reflecting the customary understanding between countries engaged in trade negotiations that the negotiations should be carried out in private."⁴⁵ Consequently, following each round of talks, very little information was disclosed to the general public.⁴⁶

While the involved parties did not freely provide the public with specific updates following each round of talks, there were limited opportunities for public input into the process. The USTR solicited public input from "interested individuals, organizations, and businesses before entering into the talks," as well as from "scores of individual advisors from outside government who serve as members of the Administration's many trade-advisory committees."⁴⁷ Critics of the lack of transparency in the negotiation process have interpreted the phrase "interested individuals, organizations, and businesses" to mean lobbyists and other influential corporate entities.⁴⁸

The general procedure at each of these rounds involved the United States' representative circulating a proposal on which each of the other representatives would make notes in the hope of deriving a consensus.⁴⁹ Following each round, the trade representatives consulted with advisors in order to further narrow down provisions, before returning to the next round of talks, which were usually held weeks or months apart.⁵⁰

43. FOREIGN AFFAIRS, TRADE, AND DEVELOPMENT CANADA: FREE TRADE AGREEMENTS (2015), <http://www.international.gc.ca/trade-agreements-accords-commerciaux/agr-acc/tpp-ptp/rounds-series.aspx?lang=eng> [<http://perma.cc/68MX-A5JK>] (archived Feb. 26, 2015).

44. *Id.*

45. OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, FACT-SHEET: THE UNITED STATES IN THE TRANS-PACIFIC PARTNERSHIP: INCREASING AMERICAN EXPORTS, SUPPORTING AMERICAN JOBS (2012) [hereinafter FACT-SHEET], <https://ustr.gov/about-us/policy-offices/press-office/fact-sheets/2012/june/transparency-and-the-tpp> [<https://perma.cc/DY7R-2CL6>] (archived Mar. 3, 2015).

46. DePilis, *supra* note 5 ("[T]alks, as with all trade agreements, have been conducted largely in secret."); Harris, *supra* note 40 ("[T]he talks have been largely shrouded in secrecy.").

47. FACT-SHEET, *supra* note 45.

48. *Id.*

49. *Id.*

50. *Id.*

Despite multiple predictions that the TPP parties would reach a finalized agreement at various proposed deadlines, a consensus was not reached until October of 2015.⁵¹ For example, after the round of talks that took place in Washington, DC, in December of 2014, Darci Vetter, the chief agricultural negotiator for the USTR, indicated that negotiations were “entering the end game,” identifying several specific provisions as the final remaining unsettled points, including sanitary and phytosanitary measures, intellectual property, and tariff negotiations.⁵² By that point, several previously looming obstacles had already dissipated, such as the United States’ approach to tobacco trade—a sticking point for Australia, who had recently passed strict tobacco sale legislation—as well as Japan’s reluctance to come to terms with the United States on an agreeable automobile tariff policy.⁵³

C. Points of Contention Among Signatories

Despite the secrecy of the negotiations, multiple leaks about the negotiations gave the public insight into the various disputed negotiating points.⁵⁴ The final agreed-upon TPP document contained thirty chapters, including topics such as Market Access, Sanitary and Phytosanitary Standards, Investment, Rules of Origin, Business Facilitation and Competition, Trade Remedies, and Intellectual Property Rights.⁵⁵

Some of the more contentious topics were intellectual property, the protocol for dealing with enterprises that are currently state-owned, market access and tariffs, investor-state dispute resolution, and tobacco trade.⁵⁶ Because the United States was negotiating from the standpoint of increased competition, some governments that owned sizeable sectors of their national economies struggled to come to terms with demands made by the United States that they began to limit their public support for those sectors.⁵⁷ In addition, while the parties negotiated dropping all tariffs between member states, the

51. *Id.*; Calmes, *supra* note 3, at 1.

52. Keith Good, *AgriTalk* (Dec. 14, 2014), <http://farmpolicy.com/wp-content/uploads/2014/12/AgriTalk14Dec16Trade.pdf> [<http://perma.cc/6XRL-XVV9>] (archived Feb. 26, 2015).

53. *Id.*

54. OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, THE TRANS-PACIFIC PARTNERSHIP, <https://ustr.gov/tpp/#text> [perma.cc/R35E-V2S3] (archived Feb. 2, 2016); Woollacott, *supra* note 11; see FERGUSSON, TPP, *supra* note 2, at 40–41.

55. Good, *supra* note 52.

56. DePilis, *supra* note 5.

57. *Id.* (citing Vietnam, Singapore, and Malaysia, specifically).

United States and Japan struggled to come to an agreement over agricultural and automobile tariffs between their two nations.⁵⁸

Among the contentious issues that arose during negotiations, perhaps the most contentious was the issue of intellectual property rights.⁵⁹ WikiLeaks has, on three separate occasions, leaked negotiators' copies of the intellectual property chapter.⁶⁰ The first leak occurred in November 2013 and the second in October 2014.⁶¹ The later leak included documents taken from the twentieth round of negotiations, which were held in Ho Chi Minh City, Vietnam, in May 2014.⁶² Unlike the final document that was leaked in October 2015, these first two drafts contained negotiators' notes regarding specific propositions and the positions each party had taken on various issues, ultimately revealing at least nineteen major points of disagreement, largely between the United States and the other parties.⁶³

To begin, the TPP is considered to be a "TRIPS Plus" agreement.⁶⁴ TRIPS is the Agreement on Trade Related Aspects of Intellectual Property Rights, which has, since 1996, defined the global minimum set of intellectual property requirements as established by the World Trade Organization.⁶⁵ The TPP is based upon TRIPS but expands on it in several key areas.

Based on the leaked negotiator drafts, the United States appeared to have been the driving force in seeking to expand intellectual property rights and protections among its negotiating partners.⁶⁶ One of the major proposed changes involved establishing

58. Asahi Shimbun, *Japan Compromising on U.S. Auto Tariffs for TPP Negotiations*, JAPANESE L. BLOG (Mar. 5, 2013), <http://ajw.asahi.com/article/business/AJ201303050069> [<https://perma.cc/6Y83-F7KD>] (archived Mar. 3, 2016).

59. See FERGUSON, TPP, *supra* note 2, at 19.

60. TPP Leak 1, *supra* note 8; TPP Leak 2, *supra* note 8; TPP Leak 3, *supra* note 9.

61. TPP Leak 1, *supra* note 8; TPP Leak 2, *supra* note 8.

62. TPP Leak 1, *supra* note 8; TPP Leak 2, *supra* note 8.

63. See generally TPP Leak 2, *supra* note 8 (exposing the contents of a confidential draft treaty describing how Intellectual Property would be handled under the TPP); see also Woollacott *supra* note 11 (explaining that the WikiLeaks exposed major discord between TPP parties).

64. Amer Raja, *Trans-Pacific Partnership Discussion on TRIPS-Plus Standards*, AM. U. INTELL. PROP. BRIEF (Nov. 17, 2011), <http://www.ipbrief.net/2011/11/17/trans-pacific-partnership-discussion-on-trips-plus-standards/> [<https://perma.cc/4RX7-ZD6X>] (archived Feb. 12, 2016); see also *Trips, Trips Plus, and Doha*, MEDECINS SANS FRONTIERES (July 2011), <http://www.msfacecess.org/content/trips-trips-plus-and-doha> [<https://perma.cc/LMN5-AUUT>] (archived Feb. 12, 2016) (describing how TRIPS plus provisions require tougher patent laws).

65. Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round, art. 1 [hereinafter TRIPS].

66. See FERGUSON, TPP, *supra* note 2, at 29 (explaining how the U.S. has sought increased intellectual property rights (IPR) protection in its FTAs).

a new minimum copyright term for signatories.⁶⁷ Currently, the TRIPS Agreement mandates a minimum copyright period of fifty years from the death of the author.⁶⁸ The United States sought to extend this protection to at least match the copyright period shared by the United States, Peru, and Chile, which is seventy years after the death of the author. The documents indicated that the figure of one hundred years from the death of the author (the copyright term in Mexico) had also come up in talks.⁶⁹ The final leaked document indicated that the final, agreed-upon term would, in fact, be life plus seventy years; this means that signatories, such as Japan, Malaysia, and New Zealand, that currently operate under a life plus fifty years regime will have to lengthen their terms accordingly.⁷⁰

In addition, the United States successfully sought not only to prohibit the removal or alteration of Digital Rights Management (DRM) from copyrighted data but also to require signatories to adopt criminal penalties for such behaviors.⁷¹ The United States also successfully lobbied for a provision that would require Internet Service Providers (ISPs) to aggressively monitor their customers for potentially infringing activity such as piracy, although it was unable to establish a regime that would hold ISPs liable for copyright infringing activity that occurred on their systems without their participation.⁷² Controversially, the United States wanted to include provisions that would require certain types of copyright infringement to be incorporated into the criminal codes of signatory nations. Ultimately, criminal classifications for infringement were limited to those occurring “on a commercial scale.”⁷³

The leaked negotiator texts also revealed how some nations resisted the implementation of U.S.-style copyright protections.⁷⁴ Australia, New Zealand, and Singapore all expressed objections to the United States’ draft of criminal copyright enforcement, seeking to

67. See TPP Leak 2, *supra* note 8, art. QQ.G.6 (demonstrating disagreements between different countries over what the minimum copyright term should be).

68. TRIPS, *supra* note 65, Part. II, § 1, art. 12.

69. See FERGUSSON, TPP, *supra* note 2, at 29; TPP Leak 2, *supra* note 8, art. QQ.G.6; see also Balfour Smith, *World Copyright Terms*, PUB. DOMAIN DAY, <http://www.publicdomainday.org/node/39> [<https://perma.cc/RWF6-A7Q9>] (archived Feb. 13, 2016) (demonstrating the length of standard copyright in different countries).

70. TPP Leak 3, *supra* note 9, art. QQ.G.6; Smith, *supra* note 69.

71. See TPP Leak 3, *supra* note 9, art. QQ.G.13(a) (describing actions that constituted violations).

72. TPP Leak 2, *supra* note 8, art. QQ.G.10(a)(ii); see also TPP Leak 3, *supra* note 9, art. QQ.H.11(I) (describing the obligations of each signatory’s government).

73. TPP Leak 2, *supra* note 8, art. QQ.H.7; TPP Leak 3, *supra* note 9, art. QQ.H.7.

74. See generally TPP Leak 1, *supra* note 8 (describing various instances in which many countries opposed proposals made by the United States); see also TPP Leak 2, *supra* note 8 (describing various points of disagreements between the United States and other nations).

replace it with text based on the Anti-Counterfeiting Trade Agreement (ACTA).⁷⁵ Both options were stricter than the provisions included in the TRIPS agreement, but the ACTA provisions, which more closely resembled the provisions in the final TPP draft, were far less rigid and provided nations with greater flexibility in enforcing IP laws.⁷⁶ For example, the United States favored criminal penalties for willful trademark infringement, counterfeiting, and piracy, regardless of whether the infringement results in a financial gain.⁷⁷ ACTA, however, only requires criminal penalties for infringements that result in financial gain.⁷⁸ Online piracy, or file sharing, are major examples of a behavior that would have been subject to criminal penalties under the proposed U.S. regime but are not under the adopted ACTA-style regime. Because file sharers do not typically gain financially when illegally download pirated data, their treatment, and potentially the treatment of their Internet Service Provider, would have been remarkably different had the United States been successful in its proposal.

An additional point of contention regarding proposed IP provisions lay in the realm of patents.⁷⁹ The United States sought to expand the definition of patentability beyond what was included in the TRIPS Agreement, which makes patents available “for any invention, whether product or processes, in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application.”⁸⁰ Put simply, the TRIPS Agreement requires novelty, an inventive step (referred to as non-obviousness in the United States), and utility. The United States sought to relax those patentability standards, permitting the patenting of plants and animals, medical methods, as well as new forms, uses, or methods of an existing product without enhanced efficacy.⁸¹ This is referred to as “evergreening,” which permits a patent-holder to effectively extend their patent term over and over again by making subtle changes that would not normally satisfy the novelty or inventive step requirement.⁸² Under both the TRIPS Agreement regime and current U.S. patent law, evergreening is not permissible.⁸³

75. FERGUSSON, TPP, *supra* note 2, at 30.

76. *Id.*

77. *Id.*

78. *Id.* at 30–31.

79. *Id.* at 30.

80. TRIPS, *supra* note 65, art. 27.

81. Krista Cox, *Evolving Patent Issues and the Trans-Pacific Partnership*, KNOWLEDGE ECOLOGY INT'L (Oct. 15, 2013), <http://keionline.org/node/1813> [<http://perma.cc/V648-LC24>] (archived Feb. 26, 2015).

82. *Id.*

83. *Id.*

Another contentious patent issue was the presumption of validity.⁸⁴ In the United States, if a patent is granted by the United States Patent and Trademark Office (USPTO), that patent is presumed to be valid in any subsequent litigation, and the burden of proof is on any accused infringer to demonstrate that the patent office mistakenly granted the patent.⁸⁵ The USPTO released data indicating that 78 percent of all granted U.S. patents contained problematic claims that either needed to be amended or canceled.⁸⁶ Not all TPP signatories have such a lax system for granting patents, and the fact that the United States was able to export a regime in which patents would be granted easily and would be costly to challenge will likely present a tremendous burden for foreign entities accused of infringement.

III. ANALYSIS

Some scholars, including the economist Joseph Stiglitz, have considered the TPP to be an unnecessary expansion of the TRIPS Agreement.⁸⁷ Many of these scholars view the lack of transparency in negotiations and the influence that pharmaceutical advisors have had as evidence that the TPP was designed specifically to benefit medical patent-holders, rather than the ultimate recipients of those medicines.⁸⁸ This Part will analyze these assertions, first by discussing some of the major changes that the TPP made to the TRIPS Agreement and how those will affect the trade of pharmaceutical goods among signatory nations. Next, this Part will analyze the effect that this change will have on the current medical regimes in signatory nations. This Part ultimately concludes that the TPP was indeed designed to benefit producers of medicines, rather than consumers, and that the trade of generic medicine will suffer dramatically.

The availability of cheap medicines will decrease globally, and pharmaceutical prices will increase. The result is that citizens in the poorer, developing signatory nations will not see increased access to health care commensurate with the proposed increase in economic

84. See *id.* (explaining that the United States wants granted patents to receive a presumption of validity).

85. *Id.*

86. *Id.*

87. See Letter from Joseph Stiglitz, Columbia Bus. Sch., to Barack Obama, President of the United States (Dec. 6, 2013), <http://keionline.org/sites/default/files/jstiglitzTPP.pdf> [<http://perma.cc/APY2-XDJQ>] (archived Feb. 26, 2015) (arguing that a TRIPS minus agreement would be more beneficial).

88. *Id.*

stature.⁸⁹ In addition, citizens of nations that currently provide access to generics through their national healthcare systems may see prices go up and availability go down.⁹⁰

This Part will first describe the ways in which the TPP expands upon the TRIPS agreement and will analyze the effects that expansion will have on the status of international IP laws. This Part will then discuss the governmental mechanisms found in India that serve as an alternative example to the TPP's mechanism for regulating generic pharmaceutical products.

A. *The Proposed TPP as a "TRIPS Plus" Regime*

Before the United States entered into the TRIPS Agreement, patents filed before June 8, 1995, received protection for seventeen years after the filing date.⁹¹ For any patent filed on or after that date, the patentee would receive protection for twenty years after the filing date.⁹² When a major pharmaceutical company, often referred to as a "pioneer drug manufacturer," applies for an initial patent, the clock starts ticking on its twenty-year protection period as soon as the application is filed, even though the company has not even begun the Food and Drug Administration (FDA)'s required approval process.⁹³ Consequently, the patent term for new pharmaceutical products has almost always run for several years—sometimes the majority of the patent period—before the drug can be legally sold to the general public. Pioneer drug manufacturers will invest time and potentially billions of dollars in developing what they hope will be a "blockbuster" pharmaceutical product. By the time the product has passed through the necessary testing and gained approval from the FDA, it is likely that years have gone by, meaning their effective patent term may be closer to a dozen or fewer years, rather than the nearly twenty that most other types of manufacturers receive.

89. See Press Release, Public Health Association, Protecting the Health of Australians in the TPPA (Feb. 18, 2014), <http://www.scoop.co.nz/stories/WO1402/S00215/protecting-the-health-of-australians-in-the-tppa.htm> [<http://perma.cc/RU67-Z58H>] (archived Feb. 26, 2015) (explaining how increased medicine costs will disproportionately affect disadvantaged groups).

90. *Id.*

91. Dennis Crouch, *Patent Term: Comparing 17-Years-from-Issue to 20-Years-from-Filing*, PATENTLYO (Dec. 12, 2010), <http://patentlyo.com/patent/2010/12/one-of-the-most-important-attributes-of-a-patent-is-its-term-or-duration-of-enforceability-in-1995-the-us-patent-system-beg.html> [<https://perma.cc/QS9R-3CAP>] (archived Feb. 13, 2016).

92. *Id.*; TRIPS, *supra* note 65, art. 33.

93. U.S.C. § 154(a)(2) (2015); see also *FDA Ensures Equivalence of Generic Drugs*, FDA (Aug. 2002), <http://www.fda.gov/Drugs/EmergencyPreparedness/BioterrorismandDrugPreparedness/ucm134444.htm> [<https://perma.cc/N4T6-LNC4>] (archived Feb. 13, 2016).

At the same time, the United States has a legal regime designed to facilitate the entry of generic drugs onto the market.⁹⁴ The Drug Price Competition and Patent Term Restoration Act, or Hatch-Waxman Act, set the stage for the manner in which generic drug manufacturers may gain permission to begin selling a generic version of a drug within the pioneer drug manufacturer's patent period.⁹⁵ Under the Hatch-Waxman Act, a generic manufacturer may apply for an Abbreviated New Drug Application (ANDA), which, if granted, gives them approval to manufacture a therapeutically equivalent version of a patented drug.⁹⁶ These applications are "abbreviated" because they do not have to include clinical data, as the safety of the medication has already been established by the pioneer drug manufacturer.⁹⁷ Generic manufacturers are able to offer medications at a much lower price than the pioneer drug manufacturer because they do not have to spend money on research and development, whereas the pioneer drug manufacturer will often charge much higher prices for an equivalent product to recoup the tremendous cost of developing the product. In order to reconcile these two regimes and continue to incentivize the production of both expensive pioneer pharmaceuticals and cheap generics, the Hatch-Waxman Act allows the pioneer patentee to apply for an additional five years of patent protection once a generic version of their product is approved for sale.⁹⁸

Another component of the Hatch-Waxman Act is an incentive for generic manufacturers to challenge pharmaceutical patents they feel are weak or invalid.⁹⁹ An interesting corollary effect of this provision is what is referred to as "reverse settlement agreements." Reverse settlement agreements are out-of-court settlements that occur in anticipation of litigation.¹⁰⁰ In the patent realm, settlements usually occur when a patent infringer pays the patent holder to not continue with an infringement claim. In contrast, reverse settlements occur when a pioneer drug manufacturer, threatened with an invalidity suit by a generic manufacturer, settles out of court, paying that generic manufacturer to *not* challenge their presumed-valid patent,

94. See generally The Hatch-Waxman Act, 21 U.S.C. § 355 (explaining lawful methods of introducing drugs into interstate commerce).

95. *Id.* § 355(j).

96. *Id.* § 355(j)(2)(A)(iv)

97. See *id.* at 40 (explaining that "labeling changes merely incorporated clinical data.").

98. See *id.* at 61 (discussing "five-year exclusive marketing period following approval of new drug application.").

99. Cox, *supra* note 81.

100. See *id.* (suggesting that reverse settlement agreements are essentially "pay-for-delay" agreements).

essentially removing them from the competitive marketplace.¹⁰¹ Reverse settlement agreements raise major antitrust concerns, and some cases have actually reached the Supreme Court on antitrust challenges.¹⁰² So far, however, the U.S. Supreme Court has not found them presumptively illegal.¹⁰³

By importing the United States' presumptive validity system for pharmaceutical patents into the TPP, several troubling changes will occur globally in relation to the availability of generic medicines. After TRIPS passed, the twenty-year patent period became the norm for most of the world.¹⁰⁴ However, not every other TRIPS signatory nation permitted a five-year extension for pharmaceuticals like the United States did. The United States sought to include the five-year extension option into the TPP, which resulted in some disagreement among the other parties.¹⁰⁵ The adoption of the U.S. system for generics entering the market may also present an additional obstacle, as it has left room for reverse settlement agreements to occur. If the ability to enter into reverse settlement agreements were to become available internationally, powerful global pharmaceuticals could potentially pay regional competitors to abstain from challenging their patents. This would allow major pharmaceuticals to further entrench their dominance in the global market, as they would now be able to pay generic medicine manufacturers to not attempt to market or produce generic versions of their products. If powerful pharmaceutical companies were able to pay small generic manufacturers to not produce competing products, the global availability of cheap generics could suffer immensely.

Another troubling change that the TPP contained was the ability to evergreen. Evergreening allows a patentee's monopoly to last much longer, perhaps even indefinitely, which delays the entry of generics into the market.¹⁰⁶ For instance, if a drug patent included a specific delivery method, but a new method is later discovered within the patent period, the patentee could reapply for a new patent on the basis that the new delivery method was novel.¹⁰⁷ This issue is exacerbated by the ability to keep pharmaceutical data secret for a

101. See *id.* (explaining how reverse settlement agreements result "in branded pharmaceutical companies paying for generic companies not to continue on the merits of the case").

102. See *id.* (discussing the Supreme Court's decision in *FTC v. Actavis*).

103. See *id.* ("[T]he Supreme Court did not rule pay-for-delay agreements to be presumptively illegal.").

104. TRIPS, *supra* note 65, art. 33.

105. TPP Leak 2, *supra* note 8, art. QQ.E.12.

106. See Margaret Flowers, *Trans-Pacific Partnership Undermines Health System*, ALJAZEERA (June 17, 2013), <http://www.aljazeera.com/indepth/opinion/2013/06/201361711230432720.html> [<http://perma.cc/R9JE-RRME>] (archived Feb. 26, 2015) (expressing concern over how evergreening may be manipulated).

107. *Id.*

period of time, preventing generic competitors from developing analogous compounds.

Both the TRIPS Agreement and current U.S. domestic patent law prohibit patent evergreening.¹⁰⁸ However, the final draft of the TPP required each signatory to make “an adjustment” available to pharmaceutical patent terms when the pharmaceutical product was subject to an “unreasonable curtailment” of the patent term due to the marketing approval process.¹⁰⁹

The TPP also permits an alternate method that could have a similar evergreening effect.¹¹⁰ This method involves permitting pharmaceutical companies to withhold their data from the public for a certain period of time. By permitting pharmaceutical companies to maintain an embargo on their experimental data, the timeline during which generic competitors could access the data and formulate biosimilar compounds is delayed.¹¹¹ President Obama’s 2014 budget proposal indicated his intention to accelerate access to generic alternatives within the United States: “[b]eginning in 2014, this proposal should award brand biologic manufacturers seven years of exclusivity, rather than twelve years under current law, and prohibit additional periods of exclusivity for brand biologics due to minor changes in product formulations, a practice often referred to as ‘evergreening.’”¹¹² Despite the President’s indication that he planned to combat domestic attempts at evergreening, the leaked negotiator drafts indicated that the United States sought to incorporate a twelve-year protection period for biologics.¹¹³ The final version of the TPP incorporated a U.S.-backed provision that would require exclusive rights over experimental data for a period of at least five years from the date of first pharmaceutical marketing approval.¹¹⁴

In addition to the five-year embargo permitted for pharmaceutical products in general, the final draft of the TPP also required signatories to adopt a minimum exclusivity period of eight years for pharmaceutical data specifically related to biologic

108. Cox, *supra* note 81.

109. TPP Leak 3, *supra* note 9, art. QQ.E.14.2.

110. Third World Network, *What’s New in the TPP Intellectual Property Text? Pharmaceutical Provisions*, PUB. CITIZEN (Oct. 9, 2015), at 6, <https://wikileaks.org/tpp-ip3/pharmaceutical/Pharmaceutical%20Provisions%20in%20the%20TPP.pdf> [<https://perma.cc/SH9P-74FB>] (archived Feb. 13, 2016).

111. Jessi Canny, *Ratifying the TPP May Be Tough, but Australia Needs It*, CONVERSATION (Oct. 6, 2015), <https://theconversation.com/ratifying-the-tpp-may-be-tough-but-australia-needs-it-48663> [<https://perma.cc/8HAA-XPBF>] (archived Feb. 13, 2016); Cox, *supra* note 81.

112. OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, BUDGET OF THE UNITED STATES GOVERNMENT, FISCAL YEAR 2014, 40 (2013).

113. See Canny, *supra* note 111 (discussing Australia’s disagreement with the United States over the twelve-year protection period).

114. TPP Leak 3, *supra* note 9, art. QQ.E.16.1.a.

compounds.¹¹⁵ Parties were also required to provide one of two potential biologic-evergreening models, one of which granted a minimum of an additional three years of data exclusivity for new indications, formulations, or methods of administering the biologic; the other model would grant at least five extra years of data exclusivity for new biologic formulations.¹¹⁶

These data exclusivity rights are independent of patent rights—a pharmaceutical research firm may keep important data secret even if their patent has already expired, or even if they never actually held a patent on the product they are researching.¹¹⁷ This presents an additional barrier to generic manufacturers, who will now have to spend time and money duplicating these trials, which could result in a delayed release of their product or a higher market price.¹¹⁸

Finally, the TPP incorporated provisions from the North American Free Trade Agreement (NAFTA), which permit pharmaceutical companies to sue governments that rejected their evergreening patent applications through an Investor-State Dispute Resolution mechanism.¹¹⁹ This means that the TPP could potentially embed the practice of pharmaceutical evergreening into the international pharmaceutical trade.¹²⁰ This would permit pharmaceutical patent-holders to apply for new patents on minor changes to their existing products, thus extending the patent monopoly and further delaying the introduction of generics into the market.

The cumulative result of these changes in international patent law may also undermine a crucial component of the TRIPS Agreement called the Doha Declaration, which guaranteed nations access to essential medicines. Added to the TRIPS Agreement in November of 2001, the Doha Declaration reads in part:

115. *Id.* art. QQ.E.20.

116. Third World Network, *supra* note 110, at 6.

117. *See Cox, supra* note 81 (discussing the detrimental effects these exclusivity rights have on competition).

118. *Id.*

119. *See* Press Release, Medecins Sans Frontieres, MSF Urges TPP Countries Not to Abandon Public Health in Bid to Finalize Trade Deal (Feb. 20, 2014) [hereinafter MSF Press Release], <http://www.doctorswithoutborders.org/news-stories/press-release/msf-urges-tpp-countries-not-abandon-public-health-bid-finalize-trade-deal> [<http://perma.cc/7RTY-2ZSG>] (archived Feb. 26, 2015) (discussing potential negative effects that the TPP may have on public health); *see also* Barbara Yu Levy, *Dispute Resolution After the TPP Agreement*, CORP. COUNS. (Oct. 15, 2015), <http://www.corpcounsel.com/id=1202739910611/Dispute-Resolution-After-the-TPP-Trade-Agreement?slreturn=20150923130450> [<https://perma.cc/VKR8-PB8P>] (archived Feb. 13, 2016) (explaining how this dispute resolution system allows investors “to challenge actions by a host country that are—or appear to be—in violation of their property rights”).

120. *See Flowers, supra* note 106 (“[T]he TPP is a major power grab by large corporations.”).

The TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.¹²¹

The Declaration continues that this “flexibility” includes “the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.”¹²² In addition, “[e]ach Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.”¹²³

The major goal of the Doha Declaration was to allow each Member state to establish its own, unchallenged regime for establishing when and how licenses are granted for medicines, as well as for whether international intellectual property rights are exhausted at their borders, stating, “These provisions in the Declaration ensure that governments may issue compulsory licenses on patents for medicines, or take other steps to protect public health.”¹²⁴

The final draft of the TPP IP chapter actually contained similar language in its opening section: “Parties may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Chapter.”¹²⁵ In addition, a subsequent section appeared to affirm a commitment to the Doha Declaration.¹²⁶

Despite these apparent affirmations of the signatory nations' right to protect the public health in their respective state, the TPP's IP provisions clearly undermine signatory governments' ability to issue compulsory licenses as guaranteed by the Doha Declaration. The only exceptions the final draft of the TPP seem to consider are for

121. World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 I.L.M. 746, art. 4 (2002) [hereinafter Doha Declaration].

122. *Id.*

123. *Id.*

124. *Id.*

125. TPP Leak 3, *supra* note 9, art. QQ.A.Y.1

126. *Id.* art. QQ.A.7.1 (“The Parties affirm their commitment to the *Declaration on the TRIPS Agreement and Public Health*.”).

HIV, tuberculosis, and malaria drugs.¹²⁷ In 2013, Medecins Sans Frontieres (MSF), a medical aid organization, wrote a letter to President Obama arguing that the TPP “will roll back public health safeguards and flexibilities enshrined in international law.”¹²⁸

In summary, the most important changes that the TPP would make to the TRIPS-mandated standards are: (i) the ability to lengthen patent terms for pharmaceutical products, (ii) the relaxation and expansion of patentability criteria for which countries must grant drug patents, (iii) the requirement for countries to issue new patents on minor alterations to a drug, and (iv) the establishment of barriers on the use of pharmaceutical test data.¹²⁹ Each of these changes will likely prevent market competition from generic drugs by making it more difficult for generics to reach market, disincentivizing the production of generics in the first place, delaying the rate at which generics may reach the market, and increasing the cost of manufacturing generics.¹³⁰ Health officials have worried that this change would primarily affect poor and developing nations that not only rely on access to cheap medicine but also often deal with epidemic outbreaks of deadly, but treatable illnesses.¹³¹ Reshma Ramachandran, a fellow with the American Medical Student Association, described the TPP as taking “the worst parts of U.S. law, the parts that make these medications unavailable to patients, and putting them into a trade policy as a guiding principle for developing countries.”¹³²

B. Potential Effects Upon International Medical Regimes

Under the IP provisions of the final leaked draft of the TPP, countries that currently make use of the TRIPS Agreement guarantee may lose their ability to issue compulsory licenses for essential medicines. In addition, pharmaceutical companies will likely be able

127. TPP Leak 3, *supra* note 9, art. QQ.A.7.1(a).

128. Letter from Dr. Unni Karunakara, Int'l President of Médecins Sans Frontieres, to Barack Obama, President of the United States (July 15, 2013) [hereinafter MSF letter], http://www.doctorswithoutborders.org/sites/usa/files/130715_TPP%20Open%20Letter_USA.pdf [<http://perma.cc/47W6-B99J>] (archived February 26, 2015).

129. *Id.*

130. *Id.*

131. See MSF Press Release, *supra* note 119 (“Make no mistake, in terms of health, the TPP remains the most damaging trade agreement we’ve ever seen, particularly for patients living in middle income countries, where the vast majority of the world’s poor people live.”).

132. Zach Carter, *Obama’s Global Health Policy Undercuts Reform at Home*, HUFFINGTON POST (July 10, 2012), http://www.huffingtonpost.com/2012/07/10/obamas-health-policy-global-health-reform_n_1659742.html [<http://perma.cc/BA98-X9YG>] (archived Feb. 26, 2015).

to sue governments that challenge their patents.¹³³ The combination of these two effects—the diminished ability to issue compulsory licenses as guaranteed by the Doha Declaration and the ability for pharmaceutical companies to sue governments that interfere with their investment in new medical patents—could lead to disastrous effects worldwide, particularly in developing countries.¹³⁴

In particular, the national health services of Australia, Canada, and New Zealand currently administer a national formulary for medicines.¹³⁵ These formularies are essentially medical boards that allow the government to reject new drugs from their public health system because the prices are too high or actually negotiate for lower prices with the patentees.¹³⁶ For example, Australia has what is called a Pharmaceutical Benefits Scheme (PBS).¹³⁷ PBS is able to regulate the price of medicine domestically, so citizens of Australia are able to pay one-third to one-tenth the price that Americans pay for many medicines.¹³⁸ Because the TPP would increase the degree of control that pharmaceutical companies have over how their products are sold, schemes like the PBS could potentially lose their bargaining power, leading to the high cost of some medicines being passed down to the patient.¹³⁹

Since 1993, New Zealand has utilized a central government agency called PHARMAC.¹⁴⁰ Since its inception, it has saved New Zealanders approximately 5 billion NZD.¹⁴¹ If the TPP passes, PHARMAC's ability buy cheap generic substitutes would be delayed and would extend the period during which PHARMAC has to rely on the original, more expensive version.¹⁴² New Zealand's government, however, has been adamant that PHARMAC's operations are "not up for negotiation."¹⁴³

133. MSF Press Release *supra* note 119; *Special Rights for Foreign Investors to Sue Governments*, AUSTL. FAIR TRADE & INV. NETWORK, LTD. [hereinafter *Special Rights*], <http://aftinet.org.au/cms/node/631> [<http://perma.cc/Y65V-AEZL>] (archived Feb. 26, 2015).

134. *Id.*

135. FERGUSSON, TPP, *supra* note 2, at 35.

136. *See* Carter, *supra* note 132.

137. *Special Rights*, *supra* note 133.

138. *Id.*

139. *See* Press Release, Public Health Association, *supra* note 89 (noting that the cost would be passed down to patients through higher costs for prescriptions).

140. ROSEMARY WYBER & W. PERRY, THE TRANS-PACIFIC PARTNERSHIP: AN ANALYSIS OF THE IMPACT ON HEALTH IN NEW ZEALAND 7 (2013), <http://www.pha.org.nz/documents/131129-tpp-nyes.pdf> [<https://perma.cc/Q4LJ-58HV>] (archived Mar. 3, 2016).

141. *Id.*

142. Gordon Campbell, *The Neutering of Pharmac—Trans Pacific Partnership: How the TPP Trade Deal Means Trouble for Our Drugs Buying Agency*, WEREWOLF (2015), <http://werewolf.co.nz/2012/11/tpp-prescribing-for-pharmac/> [<http://perma.cc/MQ2J-7TW7>] (archived Feb. 26, 2015).

143. *See* Daniels, *supra* note 28.

As for Canada, Scott Sinclair, a senior research fellow at the Canadian Centre for Policy Alternatives, argued in front of the House of Commons Standing Committee on International Trade that the TPP's patent-extension programs would cost the provincial drug plans approximately two billion CAD annually.¹⁴⁴ Under the TPP, practices like these, which allow nations to exercise leverage against pharmaceutical companies in order to lower the price their consumers pay for medicines, will likely be banned, or at least harder to utilize.¹⁴⁵

As part of the TPP's Investor-State Dispute Settlement (ISDS) regime, which has its origins in NAFTA, foreign investors, including pharmaceutical companies, can sue governments if they pass a law or policy that harms their investment, even if that law is passed in the public interest.¹⁴⁶ For example, in 2014, the American pharmaceutical giant Eli Lilly sued the government of Canada for 500 million dollars because Canada rejected two of its medicine patents.¹⁴⁷

In the developing world where nations often lack the sort of healthcare infrastructures discussed above, medicine is often provided by aid organizations, such as Medecins Sans Frontieres (Doctor's Without Borders) (MSF).¹⁴⁸ MSF estimates that it delivers healthcare in nearly seventy countries.¹⁴⁹ MSF has stated that "[g]eneric competition has proven to be the best way to reduce drug prices and improve access to treatment."¹⁵⁰ MSF utilizes generic drugs to treat HIV and AIDS and estimates that the generics have reduced the cost of treatment by nearly 99 percent.¹⁵¹ Developing signatory nations that lack the sophisticated medical infrastructure of Australia, New Zealand, or Canada may risk much more than a bargaining chip to provide cheaper medicine to its citizens. At stake here is what MSF considers "a lifeline for people in developing countries."¹⁵² Rohit Malpani, the director of policy and analysis at the MSF Access Campaign, has stated that "[t]he TPP is the most

144. Scott Sinclair, Senior Research Fellow, Canadian Centre for Policy Alternatives, Opening Remarks to the House of Commons Standing Committee on International Trade (May 27, 2013), https://www.policyalternatives.ca/sites/default/files/uploads/publications/National%20Office/2013/06/Canada_and_the_Trans_Pacific_Partnership.pdf [<https://perma.cc/NZL9-9E3B>] (archived Feb. 26, 2015).

145. *Id.*

146. Special Rights, *supra* note 133; MSF Press Release, *supra* note 119.

147. MSF Press Release, *supra* note 119.

148. MSF Letter, *supra* note 128.

149. *Id.*

150. *Id.*

151. *Id.*

152. MSF Press Release, *supra* note 119.

damaging trade agreement we have ever seen in terms of access to medicines for poor people.”¹⁵³

C. *An Outsider's Approach to Pharmaceuticals*

This subpart will focus on the approach that India has taken toward pharmaceutical giants by comparing it to that of South Africa's. In order to provide an example of the types of problems that developing signatory nations will face if the TPP passes, this subpart will first discuss the effects of evergreening in South Africa. Next, this subpart will contrast this approach to the successful approach that India has taken.

In South Africa, nearly every drug patent is granted, so aid organizations like MSF often have to spend exorbitant amounts of their budgets on name-brand pharmaceuticals.¹⁵⁴ For example, 20 percent of MSF's entire medical budget is set aside to pay for a single medication, Pfizer's Linezolid, which is an antibiotic used to treat individuals with drug-resistant tuberculosis.¹⁵⁵ A generic version of this medicine actually already exists, but due to South Africa's generous patent regime, MSF estimates that it will have to continue paying for the name brand due to Pfizer's ability to evergreen its original patent with secondary patents.¹⁵⁶

India, which is not currently a party to the TPP, has recently demonstrated how nations might utilize the flexibility embedded in the TRIPS Agreement. In 2012, the Indian government permitted a generic cancer drug to be sold for \$157 per month, rather than the \$5,000 per month price at which the pioneer drug manufacturer, Bayer, offered to sell the drug.¹⁵⁷ The Indian government calculated that during the first years of the drug's availability in India, a mere 2 percent of eligible patients received it due to its high price compared to the average Indian's income.¹⁵⁸ Subsequently, India authorized a generic manufacturer based in India, Natco Pharma, to begin selling the generic version of the drug, offering Bayer a 6 percent royalty on all sales.¹⁵⁹ Despite the fact that the right to engage in this type of compulsory licensing is expressly guaranteed by the TRIPS Agreement, in 2012, Deputy Director Teresa Rea of the USPTO testified before Congress that the United States wanted to “stop the granting of further compulsory licenses.”¹⁶⁰ The USTR did not go as

153. *Id.*

154. *Id.*

155. *Id.*

156. *Id.*

157. Carter, *supra* note 132.

158. *Id.*

159. *Id.*

160. *Id.*

far as the Deputy Director did but “expressed concern with India’s interpretation of its law in authorizing the issuance of this license.”¹⁶¹

In summary, the TPP contains IP provisions that will tremendously benefit pharmaceutical companies, while putting tremendous pressure on both the national health-care systems of developed signatory nations and the aid organizations that serve a similar role in developing signatory nations to keep up with increasing prices of name-brand pharmaceuticals and diminished availability of generic alternatives. The next Part will propose an alternative set of IP provisions, based in part on the current formulary systems of Australia, New Zealand, and Canada, as well as on the compulsory license approach that India took in dealing with Bayer. The resulting regime is an attempted compromise between national health-care systems and pharmaceutical companies, whereby citizens are still able to receive certain essential medicines at reasonable prices, while pharmaceutical companies may continue to receive royalties in order to reward them for their tremendously high research and development investments.

IV. SOLUTION

There is a pressing need for a paradigm shift in the way pharmaceuticals are researched and developed, and how intellectual property is applied to medicines as global public goods. Governments should introduce global norms which delink drug development and price. MSF believes this is essential to closing the gap in access to medicines for millions of people around the world by promoting both innovation and access.

—Medicins Sans Frontieres¹⁶²

Consistent with the International Covenant on Civil and Political Rights, this Note proposes that access to certain life-saving medications should be considered a fundamental human right and poses an alternate mechanism by which to achieve this.¹⁶³

Commensurate with the notion of life as a human right, governments should not have to choose between providing that right to its citizens and a potentially lucrative free-trade agreement with a major economic power. It is a false choice, and this Note proposes a mechanism that could be incorporated into an amended version of the TPP that would not only reaffirm the flexibility that the TRIPS

161. *Id.*

162. MSF Letter, *supra* note 128.

163. Foreclosure Relief and Extension for Service Members Act of 2014, Pub. L. No. 113-286, 128 Stat. 3093 (2014) USCS International Rights, Part III, Article 6 (PL 113-286, approved 12/18/14).

Agreement promised to its member states but also provide a framework for ensuring that adequate financial incentives remain in place for major pharmaceuticals to make the tremendous investment required for medical breakthroughs.

This Part begins by proposing a mechanism that would permit each signatory nation to create a list of National Essential Medicines and a Board that would regulate this list. Next, this Part will describe and analyze benefits and drawbacks to this mechanism as compared to the TPP as it stands.

A. *The National Essential Medicines List*

First, the TPP should incorporate an option for each signatory government to create a “Board of Essential Medicines.”¹⁶⁴ This Board could either exist as an agency of that state’s pre-existing medical formulary, or be created separately upon entering into the TPP. Upon signing the TPP, each government’s Board of Essential Medicines should be tasked with studying and identifying the most dire medical issues faced in their nation and should create a list of essential medicines that are specifically exempt from international patent rules.¹⁶⁵ These medicines would be those that the government specifically determines are most effective at treating life-threatening or terminal diseases and are intended to be available in a country’s health system at all times.¹⁶⁶ This list may be updated on a regular basis or in the case of a national health emergency, such as an outbreak.¹⁶⁷ The standard for this list should include pharmaceutical compounds that successfully treat, manage, cure, or prevent the most prevalent and dangerous preventable diseases, such as HIV/AIDS, tuberculosis, malaria, smallpox, and measles.

Because different countries face different geographic and immunological obstacles, each nation needs to be able to cater its essential medicines list to the needs of its own particular population. These medicines would include antibiotics, antivirals, vaccines, or

164. See, e.g., THE SELECTION AND USE OF ESSENTIAL MEDICINES, WHO TECHNICAL REPORT SERIES 914 (World Health Organization, 2002) [hereinafter WHO], <http://apps.who.int/medicinedocs/pdf/s4875e/s4875e.pdf> [<https://perma.cc/7CLU-JGN2>] (archived Feb. 2, 2016) (illustrating an example of a “Model List of Essential Drugs”).

165. See, e.g., *id.* § 3.3.3.

166. *Id.*

167. See, e.g., *Fast-Tracking Treatments: The Hunt for Ebola Medicines Is Being Accelerated*, ECONOMIST (Sept. 13, 2014) [hereinafter *Fast-Tracking Treatments*], <http://www.economist.com/news/science-and-technology/21616888-hunt-ebola-medicines-bein-g-accelerated-fast-tracking-treatments> [perma.cc/JS9S-4K5D] (archived Feb. 2, 2016).

other pharmaceutical methods, as long as they have high success rates associated with treating diseases with high mortality rates.¹⁶⁸

Once the list is created, the pioneer drug manufacturers will have two options. The first option would involve the pharmaceutical company granting licenses to each nation that includes the medicine on its essential medicine list. This license would permit the relevant Board of Essential Medicines to purchase the medication directly at a lower price, which they would then resell to its citizens at no profit. The pharmaceutical company would receive less money for its sales but would retain all of its original monopoly rights.

The second option would involve the pharmaceutical company freely providing its research and test data to the country directly. The country's government may then commission the manufacture of a generic alternative, the sales of which would result in a reasonable royalty to be paid back to the pioneer drug company.¹⁶⁹ In exchange for providing the information that would permit the signatory to develop a generic alternative, the pioneer would continue to be able to sell its name-brand version at its original price in that state.

This dual regime would permit each nation to either purchase and resell a name-brand medication directly at a low cost, or produce a low-cost generic alternative itself and pay a royalty back to the pioneer. In either arrangement, the original patentee would receive compensation for its tremendous research and development costs.

In terms of specific TPP provisions as they currently stand, this bargain would require other benefits for the pharmaceutical companies in order to justify the diminished profits that would result from either option. First, pharmaceutical patentees would need to continue to have the ability to evergreen all of their drug patents with secondary or continuation patents. In addition, signatory states would continue to have the option of granting a five-year extension to drug companies on their pharmaceutical patents. Regarding the five-year monopoly that pharmaceutical companies will have on their research and testing data, pioneer producers would retain that monopoly in all instances except those relating to essential medicines, in which case the monopoly right would be contingent upon whether they chose to issue a license or permit signatory nations to produce the generic alternative. If they simply issue a license so that the Board of Essential Medicines could purchase the name-brand medication at a lower price, then they would retain the data monopoly right. If, however, they would prefer to allow signatory

168. See generally WHO, *supra* note 164, at 38 (noting that the World Health Organization's Model list "aims to identify cost-effective medicines for priority conditions, together with the reasons for their inclusion, linked to evidence-based clinical guidelines and with special emphasis on public health aspects and considerations of value for money.").

169. See, e.g., Carter, *supra* note 132.

nations the opportunity to produce generics themselves, then they would have to share that information with the relevant generic producer.¹⁷⁰

In instances in which the pharmaceutical company opts to share the data and allow for generic production of their drug, each government could choose how that generic is produced, depending on the degree of state control in that nation. States may produce the medicine at a state-owned manufacturing facility, or they may award a domestic generic manufacturer or manufacturers the license, as India did with Natco Pharma and the Bayer anti-cancer drug.¹⁷¹ Nations would also have the option to permit multiple private manufacturers to bid on the right to produce the generic, in the same way other sectors make use of various private entities bidding on government contracts in order to secure the lowest price.

In order to determine the appropriate name-brand price or royalty associated with the generic sale, the Board of Essential Medicines would be able to negotiate with the pioneer drug company to find an appropriate price. The maximum price that the Board of Essential Medicines would resell the name-brand medication would be capped at 50 percent of the domestic sale price (e.g., the price an American manufacturer sells its name brand drug in the United States). Regarding the generic regime, the pioneer manufacturer could sell its name-brand product at its market value to customers that prefer and can afford the name-brand version, and the generic manufacturer would pay a royalty to be negotiated by the Board of Essential Medicines, with a minimum royalty of 6 percent.¹⁷²

170. *Id.*

171. *Id.*

172. Carter, *supra* note 132. This 6 percent starting point is based upon the royalty that Natco Pharma paid to Bayer in India.

Figure 1.

	<i>First Regime</i>	<i>Second Regime</i>
<i>Pioneer benefits regarding essential medicines</i>	Sell its own product, but at a negotiated lower price. Gets to keep its monopoly on data.	Sell its own product, at full price, and gets a reasonable royalty for generics.
<i>Generic alternative available?</i>	Not until the patent expires.	Immediately, with a royalty paid back to the pioneer.
<i>Signatory benefits regarding essential medicines</i>	Purchase and resell name-brand medications at a low price.	Manufacture and sell cheap generic alternatives.
<i>Pioneer rights under the TPP</i>	Evergreening, optional 5-year extension on patent, 12-year data monopoly on all pharmaceutical patents	Evergreening, optional 5-year extension on patent, 12-year data monopoly only for products not deemed essential
<i>How is essential medicine made available?</i>	Purchased directly by Board of Essential Medicines and resold.	Contract for generic alternative provided through bidding, state-run manufacturer, or a state-delegated private manufacturer.
<i>How is price/royalty determined?</i>	Board of Essential Medicines negotiates with pioneer, cap at 50 percent of domestic price.	Generic manufacturer sets price, Board of Essential Medicines negotiates royalty with pioneer, minimum royalty 6 percent.

In addition, each time a pioneer updates or attempts to evergreen its patent, the Board of Essential Medicines would have the right to renegotiate on a case-by-case basis as to whether the new version of the drug was sufficiently useful for the Board to invest in or add it to its list of essential medicines.¹⁷³ This way, the name-brand drugs should still be available to consumers that prefer to pay the premium. The resulting generics would compete with those name-brand drugs.

173. See WHO, *supra* note 164, § 3.3.3 (highlighting the selection criteria of the World Health Organization).

B. Projected Benefits of the Proposed Alternative

Each signatory party considering ratifying the TPP is currently faced with a decision: either maintain its current access to national health care, compulsory licensing, and cheap generics, or implement a global trade agreement that could potentially increase its GDP. This is a false choice, and the goal of this proposed regime is to permit TPP signatories to have it both ways. These countries should be free to engage in this free trade agreement while maintaining a position that affordable health care is a human right.¹⁷⁴

The goal of this scheme is to promote international pharmaceutical trade, innovation, manufacturing, and global access to affordable life-saving medicines. Under the current TRIPS Agreement scheme, compulsory licenses to produce cheap generics are available to signatories.¹⁷⁵ Under the proposed scheme, either compulsory licenses would be granted automatically or test data would be freely disseminated, permitting cheap dispersal of name-brand medications, rapid and cost-effective domestic production, and allowing for the availability of generic versions of essential medicines. Global health crises could be dealt with much more quickly and with greater effectiveness if obstacles to the production of useful generics were removed.¹⁷⁶

This plan also permits pharmaceutical companies to retain their incentives to invest in new medicines. By limiting the essential medicines list to a targeted set of specific illnesses or outbreaks, rather than taking a blanket approach to all medications, pharmaceutical companies' interests will suffer as little harm as possible. Pioneer pharmaceutical companies will be able to benefit at all tiers of medical sales and will have the ability to retain all the expanded rights proposed under the TPP.

While the generic versions will admittedly earn the pioneer a mere percentage of a lower price, the sheer number of sales that take place should make a tremendous difference toward helping the pioneer recoup its research and development cost. To use the example of Bayer and India—Bayer sold its name-brand product at roughly \$5,000 per month and was only able to reach 2 percent of eligible Indian customers.¹⁷⁷ Under the current regime, that would be the

174. See MSF Letter, *supra* note 128 (arguing that governments should introduce global norms that delink drug development and price because “MSF believes this is essential to closing the gap in access to medicines for millions of people around the world by promoting both innovation and access”).

175. Doha Declaration, *supra* note 121.

176. See Fast-tracking Treatments, *supra* note 167 (explaining that the strategy endorsed by the WHO which concluded that, provided certain conditions are met, it would be ethical to offer unproven, experimental treatments or methods to prevent infection).

177. Carter, *supra* note 132.

only price available for the first several years, and depending on the standard of living of the consumer, Bayer might never expand beyond 2 percent of its potential market. Under the regime described above, Bayer would be able to earn money from the other 98 percent of the market. While the amount of money Bayer would earn would be relatively little, it would still be more than what it would earn had it never accessed that market in the first place. An analogy would be the approach that airlines take when selling seats at different prices. If airlines only sold first class tickets, they would make a lot of money from relatively few customers. By selling coach tickets at a discounted rate, they are able to make more money by reaching a broader market, even if the additional money only amounts to a fraction of the premium-tier profit.

An additional benefit is that this plan does not disturb the decreased patentability standards under the TPP, the potential for evergreening, or the five-year extension option for pharmaceutical patents. The overarching goal is to promote cheap access to a specific set of essential medicines, not to prevent pharmaceutical companies from making money. Permitting these pharmaceutical companies to maintain tighter control over their intellectual property while providing a clear pathway for specific medications to become readily available is a reasonable trade-off.

Perhaps the most obvious benefit is what this plan will provide to the citizens of TPP signatory nations. A healthy workforce is a productive workforce, and by making life-saving medications widely available, each nation will decrease the tax burden allocated to health-care costs and will have a population that will keep up in productivity in the twenty-first century.¹⁷⁸

C. Projected Downsides of Proposed Alternative

This plan is far from perfect. Many major pharmaceutical companies in the world are headquartered in the United States and comprise a major sector of the American economy.¹⁷⁹ Permitting these companies to share in the profits earned from their astronomically expensive investment in developing their products could positively affect their incentive to discover and produce new

178. WORLD HEALTH ORGANIZATION, WORKPLACE HEALTH PROMOTION, OCCUPATIONAL HEALTH, http://www.who.int/occupational_health/topics/workplace/en/index1.html [<http://perma.cc/D6TK-8MXV>] (archived Feb. 2, 2016).

179. See, e.g., PMLIVE, TOP 25 PHARMA COMPANIES BY GLOBAL SALES (2014), http://www.pmlive.com/top_pharma_list/global_revenues [<http://perma.cc/97R2-ALUD>] (archived Feb. 2, 2016); see also PHARMA, THE BIOPHARMACEUTICAL INDUSTRY HELPS STRENGTHEN THE U.S. ECONOMY [hereinafter *The Biopharmaceutical Industry*], <http://www.pharma.org/economic-impact> [perma.cc/4C7P-CNU8] (archived Feb. 2, 2016).

medicines.¹⁸⁰ Furthermore, the success of this plan will depend on the widespread sale of the pharmaceutical products. The more successful the products, the more attractive this plan would be to pioneers. Without substantial guarantees that they would be able to recoup a substantial portion of their investment, it is unlikely pharmaceutical companies would support this plan. This proposed plan to increase access to medicines worldwide could ironically result in the diminished production of new medicines in the future without additional domestic economic incentives to continue research and development.¹⁸¹

For the foregoing reasons, it is unlikely that the United States would ever adopt this scheme. Because the United States was the dominant negotiating party in the TPP, a lack of U.S. support for a major modification such as this would smother any chance of its adoption. Pharmaceutical companies are major donors to political campaigns and are suspected of being advisors to the USTR.¹⁸² Based on its participation in the actual TPP negotiations and the comments made by the USTR Deputy Director regarding India's exercising its right to take a compulsory license, it appears that the U.S. pharmaceutical industry is hostile to any policy that would loosen its grip on its intellectual property, even if in a specific and limited way.¹⁸³ The combination of the pharmaceutical industry's hostility and influence in U.S. politics would hamper the United States' ability to engage in any future negotiations that would open pharmaceutical companies up to greater competition, even if any current or future administration were to actually accept this proposal.

The most severe drawback to this plan is how limited in scope it is. For this plan to have any practical chance of survival, however, it must be limited to a small subset of essential medicines, rather than opening up each pharmaceutical company's entire inventory of products to becoming available as generics.

Despite the obstacles, recent developments regarding international medical crises have revealed the potential for the international community to come together and address medical necessities as they arise, potentially paving the way for a mechanism like this in the future.¹⁸⁴

180. See The Biopharmaceutical Industry, *supra* note 179 (noting the importance of a "vibrant and strong" biopharmaceutical industry).

181. See, e.g., *id.*

182. See Letter from Joseph Stiglitz, *supra* note 87.

183. Carter, *supra* note 132.

184. See Fast-Tracking Treatments, *supra* note 167 (observing, using Ebola containment as an example, that "scientists and health officials will have to bypass many of the existing rules that govern the delivery of new drugs, and develop potential remedies with unprecedented speed.").

V. CONCLUSION

The TPP is the largest free-trade agreement that the United States has ever joined, and it will have massive repercussions for all parties involved, particularly regarding the availability of cheap, generic medications.¹⁸⁵ The TRIPS Agreement has guaranteed access to medication since the Doha Declaration of 2001, and unfortunately, the TPP will almost certainly end up undermining that guarantee.¹⁸⁶

If instead the negotiators adopted a plan that recognized life-saving medication as a human right, the Doha Declaration would continue as a bedrock guarantee that signatories would continue to have access to medications that could dramatically improve the health of their domestic workforces and would permit each nation to fully reap the other economic benefits the TPP offers. By limiting the essential medicine lists to a select few truly necessary medications, the TPP would not alienate pharmaceutical companies, as they would continue to benefit from their normal repertoire of products and would continue to receive strong protection of their intellectual property. They would also maintain the incentive to continue to invent and create world-changing medical products. As it currently stands, the influence that pharmaceutical companies have had on the negotiations indicates that global health will suffer if the TPP is passed. This need not be so; there is a better way of moving forward.

*Alexander Stimac**

185. FERGUSON, TPP, *supra* note 2.

186. Doha Declaration, *supra* note 121.

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